# PSJ3

# Exhibit 481A

**Healthcare Distribution Management Association**
**Government and Public Policy Council (GPPC)**
**& Specialty and Biotech Distributors Council (SBDC) Meeting**

**September 17-18, 2012**

**K & L Gates LLP**
**1601 K Street, NW**
**Washington, DC 20006**
**(202) 778-9000**

# AGENDA

**Monday, September 17**

**6:00 – 9:00 pm** **Welcoming Reception/Dinner for IRC/GPPC/SBDC**
P.J. Clarke's
1600 K Street, NW
Washington, DC
202-463-6630

**Tuesday, September 18**

**7:30 am** **Breakfast – Room 1A**
Offices of K&L Gates, 1601 K Street, NW, Washington D.C

**8:00-8:15 am** **Welcome and Introductions – Room 1A** **TAB 1**
John Gray, HDMA President & CEO
- Review Anti-trust & Anti-harassment Policy
- Review Agenda, Council Co-Chairs

GPPC
Greg Drew, Value Drug
Ann Berkey, McKesson

SBDC
Gayle Johnston, CuraScript SD
Walter Shikany, Health Coalition, Inc.

IRC
Chris Smith, HD Smith

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|---|---|---|
| | **Joint IRC/GPPC/SBDC Session – Room 1A** | **TAB 2** |
| ***8:15-8:30 am*** | ***Overview of Congressional Calendar/Priority Objectives for Remainder 112th Congressional Session***<br>• Linda Tarplin, Tarplin, Downs & Young<br>• Buddy Menn, Brown Rudnick | |
| ***8:30-9:00 AM*** | ***Overview of the Reimbursement Policy Landscape***<br>• Jennifer Young, Tarplin, Downs & Young<br>• Larri Short, Esq., Arent Fox | |
| | **GPPC/SBDC Breakout Session – Room 9A** | |
| **9:15-9:20 am** | **Approve Minutes from May GPPC Meeting** | **TAB 3** |
| **9:20-9:35 am** | **Drug Shortages/Gray Market** | **TAB 4** |
| **9:35-9:45 am** | **ASP Prompt Pay Discount** | **TAB 5** |
| **9:45-10:00 am** | **Potential for LIFO Repeal** | **TAB 6** |
| **10:00-11:15 am** | **Overview of Controlled Substances Abuse and Diversion Initiative** | **TAB 7** |
| **11:15-12:00 pm** | **Update on Federal Pedigree Activities**<br>*Speical Guest* - Keith Flanagan, Senior Health Counsel, U.S. Senate Committee on Health, Education, Labor & Pensions (HELP) | **TAB 8** |
| **12:00-1:30 pm** | **Joint Luncheon w/Guest Speaker – Room 1A**<br>Tucker Carlson, Contributor, FOX News; Editor-in-Chief, The Daily Call; Senior Fellow, The Cato Institute | **TAB 9** |
| | **GPPC/SBDC Breakout Session – Room 9A** | |
| **1:30-2:00 pm** | **Reimbursement Issues**<br>• CMS activity on National Average Drug Acquisition Cost (NADAC)<br>• National Average Retail Price (NARP) surveys | **TAB 10** |
| **2:00-2:30 pm** | **Regulatory Affairs Update**<br>• DOT Proposed Rule on Totes Labeling<br>• USP Draft Distribution Practices Initiative | **TAB 11** |
| **2:30-2:45 pm** | **Advocacy/PAC update** | **TAB 12** |
| **2:45-3:00 pm** | **Setting Priorities for 2013 HDMA Dashboard** | **TAB 13** |
| **3:00 pm** | **Adjourn** | |


# ANTITRUST POLICY

It is the unqualified policy of HDMA and all of its operating committees to conduct their operations in strict compliance with the antitrust laws of the United States.

HDMA's antitrust policy prohibits any discussions which constitute or imply an agreement or understanding concerning: 1) prices, discounts, or terms or conditions of sale; 2) profits, or profit margins or cost data; 3) market shares, sales territories or markets; 4) allocation of customers or territories; 5) selection, rejection or termination of customers or suppliers; 6) restricting the territory or markets in which a company may resell products; 7) restricting the customers to whom a company may sell; or 8) any matter which is inconsistent with the proposition that each member company of HDMA must exercise its independent business judgment in pricing its services or products, dealing with its customers and suppliers and choosing the markets in which it will compete.

HDMA membership, Board of Directors and committee meetings shall be conducted pursuant to agendas distributed in advance to attendees; discussions shall be limited to agenda items which have been reviewed by HDMA legal counsel; there shall be no substantive discussions of HDMA matters other than at official meetings; and minutes shall be distributed to attendees promptly upon review by HDMA legal counsel.

Healthcare Distribution Management Association

**SEXUAL AND OTHER UNLAWFUL HARASSMENT POLICY**
(FROM HDMA'S Employee Policy and Procedures Manual, effective April 2010)

It is HDMA's policy that all of our employees should enjoy a work atmosphere free from all forms of discrimination, including sexual or other unlawful harassment.

HDMA prohibits harassment of its employees by anyone: supervisors, other employees, members, vendors, visitors or any other business contacts. Employees are similarly prohibited from harassing coworkers, members, vendors, visitors or any other business contacts. This policy applies at HDMA's offices and also to company-sponsored events, offsite meetings, business travel, and occasions where employees gather or interact.

**1. Sexual Harassment**Error! Bookmark not defined.

The EEOC has defined sexual harassment as unwelcome sexual advances, requests for sexual favors, and other verbal or physical conduct of a sexual nature when (1) submission to such conduct is made either explicitly or implicitly a term or condition of an individual's employment; (2) submission to or rejection of such conduct by an individual is used as the basis for employment decisions affecting such individual; or (3) such conduct has the purpose or effect of unreasonably interfering with an individual's work performance or creating an intimidating, hostile or offensive working environment.

Conduct that may constitute sexual harassment includes, but is not limited to:

- Promising, directly or indirectly, an employee a reward if the employee complies with a sexually-oriented request;
- Threatening, directly or indirectly, to take action against an employee if the employee refuses to comply with a sexually-oriented request;
- Engaging in sexually suggestive physical contact, including touching another employee in a way that is unwelcome;
- Making unwanted sexual or romantic advances toward an employee, or persisting in such conduct despite the employee's rejection of the advances;
- Abusive language related to an employee's sex, including sexual innuendoes and slurs;
- Suggestive, derogatory or insulting comments or sounds, including whistling and obscene gestures;
- Comments about someone's body;

- Jokes, cartoons or pictures of a sexual nature or concerning gender-specific traits;
- Disparaging or demeaning comments about gender; and
- Words or pictures describing or displaying pornographic or sexually explicit material.

2. **Other Unlawful Harassment**Error! Bookmark not defined.

Unlawful harassment based on protected characteristics other than sex also is prohibited. Harassment based on categories other than sex can be defined as verbal or physical conduct that denigrates or shows hostility or aversion towards a protected group or against an individual because of membership in such a group, when that conduct:

- Has the purpose or effect of creating an intimidating, hostile or offensive working environment;
- Has the purpose or effect of unreasonably interfering with an individual's work performance; or
- Otherwise adversely affects an individual's employment opportunities.

Conduct that constitutes unlawful harassment on the basis of an individual's legally protected characteristics includes, but is not limited to:

- Epithets, slurs or negative stereotyping;
- Threatening, intimidating or hostile acts based on an individual's membership in a protected class;
- Denigrating jokes, cartoons or pictures based on legally protected characteristics;
- Display or circulation in the workplace of written or graphic material (including email) that denigrates or shows hostility or aversion towards an individual or group based on a protected category.

3. **Complaint and Investigation Procedures**Error! Bookmark not defined.

It is the responsibility of each employee to enforce and comply with these policies. If you believe you have been harassed or discriminated against or have witnessed or been told about discrimination or harassment in violation of these policies, you must immediately notify the Director, HR, the President or any member of management with whom you feel comfortable. Supervisors have an obligation to report all incidents of possible discrimination or harassment which they experience, witness or of which they become aware. Any supervisory employee who experiences, witnesses or becomes aware of harassment and fails to report it to the Director, HR or the President will be disciplined up to and including termination.

HDMA will conduct a thorough, impartial and prompt investigation of all complaints. Investigations will typically be conducted by Director, HR. A complaining employee may be asked to put his or her complaint in writing in order to assist with the investigation. The investigation normally will include discussions with the complaining party, any other person who experienced or witnessed the alleged discriminator or harassment, and the accused. Relevant

documents also may be reviewed. Upon completion of the investigation, if any discrimination or harassment in violation of these policies is found to have occurred, HDMA will take prompt and effective remedial action to stop the discrimination or harassment, including without limitation disciplining and/or discharging employees who have violated the policy. If a non-employee is found to have violated one of these policies, HDMA will also take effective remedial action to the fullest extent feasible. Generally, the employee who initiated the complaint will be informed of the outcome of the investigation. However, specific disciplinary action taken against any employee as a result of the investigation will not necessarily be disclosed.

HDMA will protect the confidentiality of the complaining employee, witnesses and the accused except to the extent necessary to conduct a thorough investigation or to remedy a problem discovered as part of the investigation. We also request that anyone complaining of harassment or participating in an investigation as a witness maintain the confidentiality of the investigation.

It is unlawful to retaliate against an employee for filing a complaint of harassment or for cooperating in an investigation of such a complaint. HDMA strictly prohibits retaliation or discrimination in any form against anyone who, in good faith, has reported harassment or discrimination, or who has participated in any manner in an investigation under this policy. Any person who believes they have been improperly retaliated or discriminated against in violation of this policy should follow the complaint procedure set forth above.

If you have any questions about this policy, please contact the Director, HR.

**COMPLAINTS AT HDMA OFF SITE MEETINGS SHOULD BE IMMEDIATELY DIRECTED TO HDMA'S VICE PRESIDENT, MEETINGS & CONFERENCES.**

Violations may also be reported in any of the following ways:

- Directly to the in-house Compliance Officer
- Directly to the Director, HR
- Anonymously through the toll free Whistleblower Hotline: 800-398-1496
- Anonymously through E-mail to: reports@lighthouse-services.com
- Anonymously through the Web: lighthouse-services.com (click on Report Incident link).
- Username: HDMA and Password: 901Glebe

When using the anonymous reporting system, your complaint will be recorded by a third party vendor, which will relay the information to the Compliance Officer.

As of 8/23/2010

8/31/2012

HDMA
Healthcare Distribution Management Association

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# Overview of Congressional Calendar/Priority Objectives for Remainder 112th Congressional Session

# Overview of the Reimbursement Policy Landscape

***There are no written materials for this section***

# HEALTHCARE DISTRIBUTION MANAGEMENT ASSOCIATION

# GOVERNMENT AND PUBLIC POLICY COUNCIL (GPPC) AND SPECIALTY & BIOTECH DISTRIBUTORS COUNCIL (SBDC) MEETING MINUTES

## May 15, 2012
## Teleconference

## 1) ATTENDEES

### a) COUNCIL MEMBERS PRESENT

| | |
|---|---|
| Cassi Baker | Vice President, State Government Relations<br>Cardinal Health, Inc. |
| Ken Couch | President<br>Smith Drug Company |
| Michael DiBello | Director, Regulatory Affairs<br>Henry Schein, Inc. |
| Margaret Glazier | Legal Coordinator<br>Burlington Drug Company, Inc. |
| Scott Johnson | Group & associate General Counsel<br>AmerisourceBergen Corporation |
| Gayle Johnston | President<br>CuraScript SD Specialty Distribution, An Express Scripts Company |
| Ron Lanton | Government Affairs Counsel<br>H.D. Smith |
| David Moody | Chief Executive Officer<br>Mutual Wholesale Drug Co. |
| Rita Norton | Vice President, Government Affairs<br>AmerisourceBergen Corporation |
| Samir Shah | Vice President, Regulatory Affairs<br>Harvard Drug Group |
| Connie Woodburn | Senior Vice President, Government & Community Relations<br>Cardinal Health, Inc. |
| Chris Zimmerman | Vice President, Corporate Security and Regulatory Affairs<br>AmerisourceBergen Corporation |

### b) HDMA STAFF, COUNSEL AND GUESTS

| | |
|---|---|
| Patrick Kelly | Senior Vice President, Government Affairs |
| Anita Ducca | Senior Director, Regulatory Affairs and Healthcare Policy |
| Dan Bellingham | Senior Director, State Government Affairs |
| Kristen Freitas | Director, Federal Government Affairs |
| Elizabeth Lankford | Manager, State Government Affairs |
| Jewelyn Wellborn | Manager, Federal Government Affairs |
| Allison Wiley | Regulatory Affairs & Healthcare Policy Analyst |
| Tish E. Pahl | Olsson Frank Weeda Terman Matz PC |
| Nancy McNally | Van Ness Feldman |
| Martha Russell | Assistant General Counsel, Cardinal Health, Inc. |

## 2) MEETING PROCEEDINGS

### a) Welcome Introductions & Council Administration

Patrick Kelly welcomed members to the Government and Public Policy Council (GPPC) and Specialty & Biotech Distributors Council (SBDC) teleconference at approximately 2:00 p.m. on May 15, 2012. Self-introductions and roll call followed. Tish Pahl, counsel to HDMA, reminded members that it was the policy of HDMA to conduct the call in compliance with the HDMA Antitrust and Anti-harassment policies and federal and state law.

The GPPC and SBDC co-chairs welcomed attendees and thanked everyone for their participation.

***Action:*** On motion duly made and seconded, the Minutes of the October 4, 2011 meeting of the IRC were approved as written.

### b) Federal Government Affairs Update

Patrick Kelly provided an update on HDMA's ongoing efforts regarding obtaining uniform federal pedigree and addressing track and trace issues in the context of the reauthorization of the Prescription Drug User Fee Act (PDUFA). HDMA has been working with a consortium of stakeholders interested in securing a federal standard. They have worked with the Senate HELP and House Energy and Commerce Committees. There were placeholders in the draft PDUFA reauthorization but it was not possible to achieve sufficient consensus prior to first mark-up.

FDA and the Pew Charitable Trust, who have both been actively participating in the negotiations, are focused on unit level tracking and authentication at the end user stage and they are hesitant to endorse track and trace at the lot level. Consortium members are very concerned about the unit level model. Consortium members have proposed an "Rx Tech Standard," which is a lot level tracing standard. FDA and the Pew Charitable Trust are concerned that this standard does not go far enough to meet their goals.

The relevant committees in both the House and the Senate have approved PDUFA and neither version contains pedigree. Assuming consensus can be achieved, this means that any federal pedigree provision would be offered in a manager's amendment. This is difficult, particularly with the strong desire to keep PDUFA "clean," as it is considered "must pass" legislation. This makes inclusion of federal pedigree in the final bill difficult, but not impossible. The work continues and HDMA will continue to keep members apprised of developments.

Senator McCain (R-Az.) offered an amendment on importation that was defeated, but it could be offered again. HDMA will continue to oppose any importation amendments. Senator Harkin (D-Iowa) indicated he would oppose an importation amendment. Again, the congressional effort has been to keep controversial issues out of PDUFA to assure passage.

Ms. Kristen Freitas described the timing for PDUFA. The plan is for presentation of the bill to the White House for President Obama's presumptive signature on July 4, 2012.

Ms. Freitas then addressed the issues of drug shortages and recent activity. There are numerous pieces of proposed legislation, including provisions in PDUFA, standalone proposals and discussion drafts. Staff prepared a side-by-side comparison of the different proposals. Ms. Freitas explained that HDMA's efforts are focused upon limiting any reporting obligations for distributors and the reporting of pricing and contractual information. Staff has consulted with the Federal Government Affairs Committee (FGAC) and the Specialty and Biotech Distributors Committee (SBDC).

Ms. Freitas presented on HDMA activities regarding Average Sale Price (ASP) prompt pay discounts. HDMA is working with an ASP stakeholders group that includes manufacturers, wholesalers, physicians, and patient groups who are drafting a letter to be sent to legislators urging support of ASP prompt pay legislation. HDMA will continue to monitor for any proposals to reduce ASP. Stakeholders are very concerned about the planned 2% cut coming in January 2013 under sequestration.

Ms. Freitas discussed recent staff efforts regarding the 340B program. There is a new coalition, the Alliance for Patient Focused Care, which has approached HDMA about joining. The coalition is focused upon preventing the further expansion of the 340B program while ensuring that the program continues its original purpose of meeting the needs of underserved patients. HDMA is reviewing the invitation and the matter is being discussed in the FGAC, the SBDC, and the Reimbursement Task Force. HDMA has, thus far, not taken a position on expansion of the 340B program.

Ms. Freitas reviewed the legislative efforts regarding prescription drug abuse initiatives. Rep. Bono Mack (R-Calif.) has sent a letter to the Drug Enforcement Administration (DEA) and the Department of Health and Human Services (HHS); Senators Grassley (R-Iowa) and Whitehouse (D-R.I.) have requested a Government Accounting Office (GAO) report on DEA policies and drug shortages; and Senators Baucus (D-Mont.) and Grassley (R-Iowa) have sent a letter to opioid manufacturers on marketing practices.

Ms. Jewelyn Wellborn presented regarding the efforts by Senator Manchin (D-WV) to reclassify hydrocodone combination products from Schedule III to Schedule II. HDMA is closely monitoring the legislation and educating lawmakers on the impact of reclassification on wholesalers.

**c) <u>State Government/Regulatory Affairs Update</u>**

Mr. Kelly discussed attending the National Governors Association meeting and the convening of the State Prescription Drug Abuse Reduction Policy Academy. The purpose of this program is to develop and implement comprehensive strategies to address and help mitigate

prescription drug abuse and diversion at the state level. Activities include Prescription Drug Monitoring Programs (PDMPs), disposal, enforcement initiatives, and best practices. HDMA is providing financial support for the project as it explores how to address prescription drug diversion when a significant part of the abuse problem arises because users obtain opioid drugs from friends and family members.

Dan Bellingham presented a state legislative update. State laws restricting pseudoephedrine and hydrocodone have been moving through several states this year. To date, no state has scheduled pseudoephedrine. HDMA has been successful in obtaining a storage/recordkeeping exemption in five states considering such legislation. New York, Massachusetts, and Oklahoma have proposed making hydrocodone a Schedule II substance. HDMA has obtained a storage/recordkeeping exemption in New York and Massachusetts. The Oklahoma bill does not appear to be moving toward passage, though the Board of Pharmacy indicated it would address distributor storage and recordkeeping concerns. There have also been state efforts regarding drug disposal, stricter regulation of pain clinics, and changes to PDMPs.

States have been active in adopting average acquisition cost (AAC) in Medicaid reimbursement metrics. California has "cleanup" legislation; an Iowa law is awaiting the Governor's signature; and legislation was introduced in Oklahoma but did not move. There has been activity at a regulatory level in several states. The New York Department of Health is implementing AAC, surveying pharmacies and identifying a dispensing fee; Maryland has included an AAC definition under Medicaid reimbursement; Texas has proposed AAC as a possible reimbursement methodology. HDMA has been alert for any wholesaler reporting requirements but to date none have been proposed.

**d) <u>Regulatory Affairs Update</u>**

Mr. Kelly presented a regulatory update on actions by the Centers for Medicare and Medicaid Services (CMS). HDMA submitted comments on April 2, 2012 on CMS' proposed rule regarding the Average Manufacturer Price (AMP) rule. Issues HDMA addressed in comments included: bona fide service fees, 5i drugs, federal upper limit (FUL) volatility, ensuring adequate pharmacy reimbursement, and other matters. HDMA has also been a signatory on joint letters regarding line extensions for abuse-deterrent formulations, FULs data and other matters. HDMA does not expect a final AMP rule until 2013.

Mr. Kelly discussed HDMA's belief that CMS is committed to moving toward a National Average Drug Acquisition Cost (NADAC) metric. Further, CMS is interested in seeing wholesalers as potential reporting entities. HDMA has concerns about confidentiality and the maintenance of proprietary data. CMS plans to begin NADAC data collection. It will survey pharmacies in May/June 2012, release draft data, and hold a stakeholder meeting. CMS is committed to doing a second survey.

HDMA continues to work on the AAC issues. It is developing a "Guiding Principles" document and focuses upon assuring adequate pharmacy reimbursement. Further, HDMA continues to educate on the challenges regarding data collections. HDMA expects it will continue to work with stakeholders and meet with CMS.

HDMA also submitted comments to CMS on the Physician Payment Sunshine Provisions of the Affordable Care Act. HDMA submitted comments requesting that the final rule acknowledge that the legislative intent was not to include wholesalers under the law. A final rule is expected by the end of 2012.

Ms. Anita Ducca presented on HDMA's ongoing efforts with DEA on behalf of members. DEA has still not responded to HDMA questions submitted last year. In subsequent meetings, DEA has stated it will not share ARCOS data with industry members. HDMA has met with outside counsel and will be presenting options at the next Executive Committee meeting. Options for further engagement and efforts to satisfy DEA's nebulous suspicious orders requirements include creating an ARCOS-like data base, a third-party audit program, or an algorithm and thresholds. Each approach has positive and negative attributes. Other measures include encouraging congressional inquiries and engagement, petitioning DEA, and creating positive messaging about distributors' efforts. HDMA is supporting the National Governors Association initiative and filed an amicus brief in May 2012 in the proceeding arising from DEA's revocation of a Cardinal Health establishment license.

Discussion of these and other options ensued.

Ms. Ducca explained that DEA is increasing its registration fees in order to conduct more inspections and enforcement because the agency believes abuse is increasing.

Ms. Ducca also presented briefly regarding FDA's consideration of an initiative to switch certain prescription drugs to a new category of drugs potentially not requiring a doctor's prescription but requiring a pharmacist's approval. FDA is currently in an exploratory phase on this issue. HDMA would not want to see this program develop into a quasi-REMS type program with distribution restrictions upon which pharmacies may obtain a drug.

Ms. Ducca gave a brief update on U.S. Pharmacopeia's (USP) recent guidance development on distribution practices. The final guidance, "*Guidance on Good Storage and Shipping Practices*" (2011) required significant input from distributors. USP is currently developing a new guidance, "*Good Distribution Practices – Supply Chain Integrity.*" HDMA is commenting upon this draft and has significant concerns as it appears that USP is trying to enact, through guidance, far-reaching requirements on difficult matters such as pedigree, track and trace, serialization, and authentication. HDMA work on this guidance development is ongoing; HDMA will also meet with USP to discuss concerns about the fragmented approach to such important issues.

**e) Dashboard**

Staff had circulated in advance of the meeting recommendations for changes to the GPPC/SBDC Dashboard. With insufficient time left on the call to discuss, there was consensus that staff should circulate the recommended changes via electronic mail for consideration and vote.

***Action:*** HDMA staff will circulate via electronic mail recommended changes to the GPPC/SBDC's Dashboard and ask the GPPC/SBDC to vote to approve or reject the recommendations.

**3) Conclusion**

There being no further discussion, the meeting was adjourned at 3:20 PM.

Prepared by:

_____
Tish E. Pahl, Counsel
Date: June __, 2012

Approved by:

_____
Patrick Kelly
Date: September __, 2012

HEALTHCARE DISTRIBUTION MANAGEMENT ASSOCIATION

# Testimony before the

# Senate Commerce, Science and Transportation Committee

**John M. Gray, President and CEO**

**Healthcare Distribution Management Association**

July 25, 2012

901 North Glebe Road · Suite 1000 · Arlington, VA 22203
(703) 787-0000 · (703) 935-3200 (Fax) · www.HealthcareDistribution.org

Good morning Chairman Rockefeller, Ranking Member Hutchison and Members of the Senate Commerce Committee. I am John Gray, president and CEO of the Healthcare Distribution Management Association (HDMA). Thank you for the opportunity to provide an overview of the pharmaceutical distribution system with respect to the critically important issue of drug shortages.

We applaud the Committee's efforts to address the drug shortage issue and some of the resulting symptoms, including gray market diversion of products in short supply.

For the purposes of our discussion today I will reference a recent report from the Premier Healthcare Alliance that defines the gray market as **a** parallel market, "that is unofficial, unauthorized or unintended by the original manufacturer." Given that context, and to distinguish HDMA members from the gray market, I will share with you information about the primary pharmaceutical distribution industry.

HDMA is the national association representing America's primary healthcare distributors – the vital link between manufacturers and providers in our nation's healthcare system. Approximately 90 percent of all pharmaceutical product sales in the United States flow through HDMA's 34 distributor members. Each business day, HDMA member companies ensure that more than nine million prescription medicines and healthcare products from more than 1,100 manufacturers are delivered safely and efficiently to nearly 200,000 healthcare providers including, pharmacies, hospitals, nursing homes, clinics and other healthcare entities. Our provider customers generally place orders for prescription medicines by 8 p.m. in the evening and receive deliveries from their distributors the next morning.

Wholesale distribution is defined as the "distribution of prescription drugs to persons other than a consumer or patient." HDMA members are primary wholesalers, that is our members are predominantly Authorized Distributors of Record (ADRs), as designated by pharmaceutical manufacturers. Our members purchase the majority of product directly from pharmaceutical manufacturers and sell only to appropriately licensed healthcare providers and entities.

In 1988, the Prescription Drug Marketing Act (PDMA) was enacted to increase safeguards in the drug distribution system by preventing the introduction and retail sale of substandard, ineffective or counterfeit drugs. It also helped define the pharmaceutical distribution industry as we know it today. Our distributor members operate in accordance with the requirements set forth in the PDMA, as well as licensing rules and standards in all 50 states.

HDMA and its members are strong advocates for increased wholesaler licensure standards and a uniform federal pedigree system to enhance the safety and security of the pharmaceutical supply chain. In addition to fundamentally addressing counterfeit and diverted medicines, federal pedigree may be a useful tool in discouraging gray market activities associated with drug products in short supply.

Effectively addressing a drug shortage is a difficult and complex challenge for the entire healthcare community, in large part because a shortage typically appears with little or no warning and often requires significant resources to manage. HDMA member companies are working hard to improve communications within the supply chain and, where possible, to mitigate the impact of drug shortages. Distributors do not manufacture product and so can do little about the root causes of shortages. However, distributors do play an important role by helping to coordinate and share information about drug shortages when they arise.

Distributors are typically notified of a shortage by a manufacturer or provider partner. Once information is received, distributors communicate with their manufacturer partners about product availability to understand the scope and expected duration of any shortage. They then work as quickly as possible with their customers to fill orders, to the extent they are able, usually based upon each customer's historical purchasing patterns. If necessary, distributors work with customers and manufacturers to identify alternative product options.

HDMA, in collaboration with its distributor members, manufacturers and providers, recently completed voluntary industry guidelines on improving communication between supply chain partners in the event of a product shortage. We hope this effort, in conjunction with enhanced wholesale licensure standards and a uniform federal pedigree system, will contribute to the better management of product shortage issues in the future.

HDMA is committed to working with the Congress, all relevant regulatory agencies and the entire supply chain to develop collaborative solutions that mitigate the impact drug shortages have on the most important stakeholder: the patient.

I thank you again for the invitation to participate in this hearing and hope this overview was valuable to the Committee as it explores this important and timely topic.


August 31, 2012

The Honorable John D. Rockefeller
Committee on Commerce, Science and Transportation
254 Russell Senate Office Building
Washington, DC 20510

Dear Chairman Rockefeller:

Thank you for the opportunity to testify before the Senate Committee on Commerce, Science and Transportation on July 25, 2012 at the hearing entitled "Short-Supply Prescription Drugs: Shining a Light on the Gray Market." I have attached my response to the Questions for the Record forwarded to us by your staff.

As a result of the Commerce committee hearing and release of the "*Shining Light on the Gray Market*" report, we understand that responsible pharmacies are more acutely aware of the potential impact of drug shortages on patient health and may be ending their practices of reselling product, to the extent they had previously done so. While this is a very positive development, we are encouraging our members to remain vigilant for any change in tactics from gray market suppliers. These gray market entities may pursue other avenues to obtain drugs in short supply, such as through veterinary and dental providers.

In fact, the Federal Trade Commission is convening a workshop to examine certain veterinary drug prescribing and distribution practices, including instances in which "veterinarians purchase pet medications from manufacturers or authorized distributors and then resell some portion of their purchase to secondary suppliers for a profit." 77 Fed. Reg. 40,355, 40,356 (July 9, 2012).

Thank you for your leadership and we look forward to continuing to work with you and your staff on the important issue of drug shortages.

Sincerely,

John M. Gray
President & CEO

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(703) 787-0000 • (703) 935-3200 (fax) • www.HealthcareDistribution.org

Healthcare Distribution Management Association
Response to Questions for the Record
Senate Committee on Commerce, Science and Transportation
Hearing on "Short-Supply Prescription Drugs: Shining a Light on the Gray Market"
July 25, 2012

**QFR from Senator Roger Wicker**

**Can you give us your opinion on what measures could be taken to tighten the supply chain or to prevent these types of "questionable" transactions from taking place?**

HDMA and its members are strong advocates for increased wholesaler licensure standards and a uniform federal pedigree system to enhance the safety and security of the pharmaceutical supply chain. In addition to fundamentally addressing counterfeit and diverted medicines, federal pedigree may be a useful tool in discouraging gray market activities associated with drug products in short supply.

Further, HDMA supports a prohibition on wholesalers' purchasing prescription drugs from pharmacies. When HDMA members sell any drugs (regardless of their shortage status) to pharmacies or providers, it is with the intention that the product will be dispensed or administered to a patient in the usual course of pharmacy or medical practice.

**QFR from Senator John Boozman**

**According to Dr. Coster's testimony, the NCPA encourages pharmacists to conduct due diligence on potential wholesalers before engaging in business transactions. Has HDMA developed industry guidelines to assist primary distributors in vetting their customers?**

In 2008, HDMA published the *Industry Compliance Guidelines: Reporting Suspicious Order and Preventing Diversion of Controlled Substances* (ICGs) (http://www.healthcaredistribution.org/gov_affairs/pdf_controlled/20081113_icg.pdf).

These guidelines emphasize "Know Your Customer" – that is, obtaining and reviewing thorough background information about a distributor's prospective customers prior to doing business with them. The ICGs support due diligence efforts to provide assurance that pharmacy customers are appropriately licensed by state and federal authorities and that these entities intend to dispense drug products for legally acceptable purposes.

The ICGs were specifically developed to help evaluate customer orders for controlled substances and report those that are "suspicious" to the Drug Enforcement Administration (DEA) as required under federal law[1]. These guidelines are also intended to aid distributors in evaluating and incorporating DEA interpretations of distributors' responsibilities for responding to ever-evolving changes in the diversion and illicit use of these much needed medications.

As important as it is for distributors to take responsibility to prevent diversion of controlled substances, it is equally important for all members of the supply chain (including manufacturers, dispensers, and prescribers) to take steps to help prevent drug abuse as well as preventing the diversion of product into the gray market.

[1] 21 C.F.R. § 1301.74(b).

# Bill Summary & Status
# 112th Congress (2011 - 2012)
# S.733
# Cosponsors

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**S.733**
**Latest Title:** A bill to amend part B of title XVIII of the Social Security Act to exclude customary prompt pay discounts from manufacturers to wholesalers from the average sales price for drugs and biologicals under Medicare.
**Sponsor:** Sen Roberts, Pat [KS] (introduced 4/5/2011) Cosponsors (3)
**Related Bills:** H.R.905
**Latest Major Action:** 4/5/2011 Referred to Senate committee. Status: Read twice and referred to the Committee on Finance.

**COSPONSORS(3), ALPHABETICAL** [followed by Cosponsors withdrawn]: (Sort: by date)

Sen Casey, Robert P., Jr. [PA] - 4/12/2011
Sen Hagan, Kay [NC] - 6/22/2011
Sen Stabenow, Debbie [MI] - 4/5/2011

# Bill Summary & Status
# 112th Congress (2011 - 2012)
# H.R.905
# Cosponsors

**Item 1 of 1**

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**H.R.905**
**Latest Title:** To amend part B of title XVIII of the Social Security Act to exclude customary prompt pay discounts from manufacturers to wholesalers from the average sales price for drugs and biologicals under Medicare.
**Sponsor:** Rep Whitfield, Ed [KY-1] (introduced 3/3/2011) Cosponsors (72)
**Related Bills:** S.733
**Latest Major Action:** 3/14/2011 Referred to House subcommittee. Status: Referred to the Subcommittee on Health.

**COSPONSORS(72), ALPHABETICAL** [followed by Cosponsors withdrawn]: (Sort: by date)

Rep Altmire, Jason [PA-4] - 5/2/2011
Rep Austria, Steve [OH-7] - 10/24/2011
Rep Barletta, Lou [PA-11] - 9/7/2011
Rep Barrow, John [GA-12] - 7/11/2012
Rep Berkley, Shelley [NV-1] - 3/29/2011
Rep Bilbray, Brian P. [CA-50] - 6/27/2012
Rep Black, Diane [TN-6] - 9/10/2012
Rep Blackburn, Marsha [TN-7] - 3/3/2011
Rep Braley, Bruce L. [IA-1] - 4/6/2011
Rep Burgess, Michael C. [TX-26] - 6/27/2012
Rep Capps, Lois [CA-23] - 7/11/2012
Rep Cassidy, Bill [LA-6] - 7/18/2012
Rep Chu, Judy [CA-32] - 9/10/2012
Rep Clay, Wm. Lacy [MO-1] - 5/10/2011
Rep Cohen, Steve [TN-9] - 4/13/2011
Rep Courtney, Joe [CT-2] - 3/3/2011
Rep DeGette, Diana [CO-1] - 3/3/2011
Rep DeLauro, Rosa L. [CT-3] - 3/3/2011
Rep Dent, Charles W. [PA-15] - 5/2/2011
Rep Fitzpatrick, Michael G. [PA-8] - 1/23/2012

Rep Flores, Bill [TX-17] - 5/8/2012
Rep Gerlach, Jim [PA-6] - 3/3/2011
Rep Gibson, Christopher P. [NY-20] - 12/19/2011
Rep Gingrey, Phil [GA-11] - 6/13/2011
Rep Gonzalez, Charles A. [TX-20] - 6/21/2011
Rep Green, Gene [TX-29] - 3/3/2011
Rep Griffin, Tim [AR-2] - 9/10/2012
Rep Griffith, H. Morgan [VA-9] - 8/2/2012
Rep Grijalva, Raul M. [AZ-7] - 4/25/2012
Rep Guthrie, Brett [KY-2] - 5/10/2011
Rep Himes, James A. [CT-4] - 3/3/2011
Rep Holt, Rush D. [NJ-12] - 5/23/2011
Rep Israel, Steve [NY-2] - 3/3/2011
Rep Jenkins, Lynn [KS-2] - 8/2/2012
Rep Johnson, Henry C. "Hank," Jr. [GA-4] - 4/6/2011
Rep Kind, Ron [WI-3] - 3/3/2011
Rep Kinzinger, Adam [IL-11] - 8/2/2012
Rep Kissell, Larry [NC-8] - 5/24/2011
Rep Lance, Leonard [NJ-7] - 3/15/2011
Rep Larson, John B. [CT-1] - 7/11/2012
Rep Latham, Tom [IA-4] - 8/2/2012
Rep Lewis, John [GA-5] - 3/3/2011
Rep Mack, Connie [FL-14] - 4/13/2011
Rep Marchant, Kenny [TX-24] - 6/19/2012
Rep Marino, Tom [PA-10] - 6/22/2011
Rep Matsui, Doris O. [CA-5] - 6/13/2011
Rep McHenry, Patrick T. [NC-10] - 4/6/2011
Rep McMorris Rodgers, Cathy [WA-5] - 5/23/2011
Rep Meehan, Patrick [PA-7] - 9/13/2011
Rep Miller, Brad [NC-13] - 4/6/2011
Rep Myrick, Sue Wilkins [NC-9] - 3/29/2011
Rep Nugent, Richard [FL-5] - 7/17/2012
Rep Nunes, Devin [CA-21] - 3/3/2011
Rep Olson, Pete [TX-22] - 6/24/2011
Rep Pascrell, Bill, Jr. [NJ-8] - 6/5/2012
Rep Pastor, Ed [AZ-4] - 5/23/2011
Rep Paulsen, Erik [MN-3] - 10/5/2011
Rep Price, Tom [GA-6] - 6/18/2012
Rep Rogers, Mike J. [MI-8] - 3/3/2011
Rep Ross, Mike [AR-4] - 7/5/2011
Rep Sanchez, Linda T. [CA-39] - 7/24/2012
Rep Schock, Aaron [IL-18] - 4/27/2012
Rep Schwartz, Allyson Y. [PA-13] - 5/26/2011
Rep Sessions, Pete [TX-32] - 3/3/2011
Rep Sewell, Terri A. [AL-7] - 3/29/2011
Rep Shimkus, John [IL-19] - 3/3/2011
Rep Thornberry, Mac [TX-13] - 7/24/2012
Rep Tiberi, Patrick J. [OH-12] - 3/3/2011
Rep Towns, Edolphus [NY-10] - 3/3/2011
Rep Walden, Greg [OR-2] - 3/29/2011
Rep Webster, Daniel [FL-8] - 6/8/2012
Rep Wittman, Robert J. [VA-1] - 12/7/2011

# LIFO Update

***There are no written materials for this section***

ONE HUNDRED TWELFTH CONGRESS

# Congress of the United States

## House of Representatives

COMMITTEE ON THE JUDICIARY

2138 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515-6216

(202) 225–3951
http://www.house.gov/judiciary

June 21, 2012

The Honorable Michele M. Leonhart
Administrator
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152

Dear Ms. Leonhart,

The Judiciary Committee's Subcommittee on Crime, Terrorism and Homeland Security held a hearing on DEA Oversight on Wednesday, June 20, 2012 at 10:00 a.m. in room 2141 of the Rayburn House Office Building. Thank you for your testimony.

Questions for the record have been submitted to the subcommittee within five legislative days of the hearing. The questions addressed to you are attached. We will appreciate a full and complete response as they will be included in the official hearing record.

Please submit your written answers to Lindsay Hamilton at Lindsay.Hamilton2@mail.house.gov by Friday, July 6. If you have any further questions or concerns, please contact Bart Forysth, at Bart.Forsyth@mail.house.gov.

Thank you again for your participation in the hearing.

Sincerely,

Lamar Smith
Chairman

**Congressman F. James Sensenbrenner, Jr.**
**Chairman, Crime Subcommittee**
**Oversight Hearing on the DEA**
**Questions for the Record**

1. Do you believe that shrinking the supply of prescription painkillers is the best method of combating abuse? Doesn't shrinking the supply do as much to prevent legitimate use as it does abuse?

2. Does the DEA offer clear guidance to industry as to what constitutes suspicious behavior that should be reported? "Suspicious Orders" are not defined in the DEA regulations. The regulations give three examples of circumstances that constitute "suspicious orders." Specifically, 21 C.F.R § 30.74(b) states:

   > The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

   Do you believe this guidance is sufficient?

3. Have members of industry asked for additional guidance on how to determine when a particular order is suspicious? If so, how have you responded?

4. Can you provide additional guidance beyond what is currently available?

**Congressman Robert C. "Bobby" Scott**
**Oversight Hearing on the DEA**
**Questions for the Record**

1. In your testimony, you described the elaborate, and no doubt expensive, efforts by DEA to combat drug cartels all over the world. Please tell me how these efforts impact domestic use of illegal drugs?

2. If you were to significantly reduce the amount of money DEA now spends on combating drug cartels such as those operating in Colombia and Mexico and instead reallocate those funds to proven drug treatment programs in the United States, would you or would you not cause a greater reduction in domestic drug use?

3. In my opening statement, I detailed how evidence suggests that, while drug use in all the major abuse categories among White Americans is as high as or higher than drug use among Black and Hispanic Americans, the vast majority of those imprisoned for drug law violations are Black and Hispanic. For example, drug use data indicates that some 60% of crack cocaine users are White while 94% of those imprisoned for crack cocaine violations are Black - 89% or Hispanic - 5%. http://www.oas.samhsa.gov/nsduh/2k4nsduh/2k4tabs/Sect1peTabs43to47.pdf. Overall, Black Americans make up 12% of the U.S population, but almost 50% of those incarcerated for illegal drug violations. Please tell me if DEA's policies and practices contribute to these racial disparities. Is DEA making any effort to address this disparate treatment of minorities? I note that, during our discussion in the question period, you did not acknowledge the problem nor indicate that DEA is doing anything to address it.

4. In response to one of my questions, you said that, in this past year, there was more money spent on prevention and treatment than there was on domestic law enforcement. Please explain what expenditures you are counting for "prevention and treatment" and for "domestic law enforcement."

**Congresswoman Judy Chu**
**Oversight Hearing on the DEA**
**Questions for the Record**

1. **Question:** What factors does the DEA take into account when determining which pharmacies are receiving excessive orders of controlled substances?

2. **Question:** Does the DEA have guidelines for wholesalers and/or pharmacies regarding what constitutes excessive orders? Does the DEA use metrics such as dosage units per month?

3. **Question:** When determining which pharmacies to target, does the DEA take into account mail order pharmacies? Mail order pharmacies dispense large quantities of controlled substances to patients they do not have a personal relationship with nor do they have a relationship with the prescribers whose prescriptions they fill.

4. **Question:** There are examples of independent community pharmacies being targeted by wholesalers/DEA for no transparent or stated reason, oftentimes resulting in all controlled substance orders being completely halted. This is causing hardships for independents who are primarily located in and serve more rural populations. Is the DEA targeting independent community pharmacies to a higher degree than chain pharmacies? There is a perception that independents are being targeted for reasons beyond their control such as a lack of ability to self ware house, perceived less stringent internal controls, and/or decreased legal capabilities, among others.

HDMA
Healthcare Distribution Management Association

# HDMA Federal and State Legislative Priorities Related to Prescription Drug Abuse
## CONFIDENTIAL – FOR INTERNAL COMPANY USE ONLY

This chart is intended to highlight potential issues that HDMA may consider supporting.

| Issue | Status | Political Perspective | HDMA Recommendation/ Policy Considerations |
|---|---|---|---|
| ***Cargo Theft/Diversion*** | **FEDERAL** - Some legislative proposals address diversion upstream in the supply chain by increasing penalties for diverting medical products in pre-retail distribution. The SAFE DOSES Act addresses these issues and includes a provision for even higher penalties for "aggravated offenses" involving an agent or organization in the supply chain for a pre-retail medical product or if violence or force is used in the process of a theft. The bill has passed the House but has not yet been acted on in the Senate.<br><br>**STATE** – The New Mexico Board of Pharmacy finalized rules in 2009 that included HDMA suggested language. No other state has passed legislation/regulations. The language requires wholesalers to only use common carriers that follow specific procedures. These include, but are not limited to, criminal background checks, high risk delivery precautions and no unapproved stops. | At the federal level, HDMA participates in the Safe Doses Coalition which is comprised primarily of manufacturers and HDMA.<br><br>At the state level, HDMA originally anticipated more states proposing similar language to New Mexico. However, we continue to monitor state activity as cargo theft gets more media coverage. HDMA worked with NACDS, NABP, PhRMA, UPS and the NM Board of Pharmacy on the final language. | HDMA currently supports efforts to increase penalties on cargo theft, as well as stronger requirements for common carriers (at the state level).<br><br>**POLICY QUESTION:** Should HDMA become more proactive in our support of cargo theft/diversion issues at the state and federal levels? |

*This chart was prepared by the Healthcare Distribution Management Association.*
*Updated September 7, 2012.*

| ISSUE | STATUS | POLITICAL PERSPECTIVE | HDMA RECOMMENDATION/ POLICY CONSIDERATIONS |
|---|---|---|---|
| ***Doctor Shopping*** | **STATE ONLY** - Separate from the pain clinic/pill mill issue, a handful of states have enacted legislation to specifically prohibit people from obtaining multiple prescriptions for controlled substances from different practitioners. For example, Arizona enacted a law that restricts a person from knowingly obtaining a prescription drug by fraud or deceit. | This issue could be an opportunity for HDMA to support an issue that has little opposition. | HDMA recommends supporting such legislation in the states when possible.<br><br>**POLICY QUESTION**:<br>Should HDMA support legislation to prohibit people from doctor shopping? |
| ***Drug Disposal*** | **FEDERAL** - In 2010, the Secure and Responsible Drug Disposal Act was signed into law to allow patients to deliver unused controlled substances "to appropriate entities for disposal in a safe and effective manner consistent with effective controls against diversion." DEA is in the process of drafting regulations to implement the Act.<br><br>Additionally, pending legislation would establish a National Pharmaceutical Stewardship Organization as a non-profit corporation to implement certification requirements facilitating the collection and disposal of drugs. Manufacturers would be required to participate or receive certification.<br><br>**STATE** - Several states and counties have introduced drug disposal proposals over the last 10 years. In July 2012 Alameda County, CA became the first | Many stakeholders support drug disposal efforts at the federal level.<br><br>While some environmental and drug abuse groups support these measures, manufacturers oppose efforts that require them to pay for and maintain the disposal program, which is an issue that is raised mainly at the state level. | HDMA currently supports efforts to ensure the safe and secure disposal of unused, unwanted or expired medications.<br><br>The issue of who pays for these disposal programs remains. HDMA currently opposes efforts to require wholesalers to pay for these programs. |

| ISSUE | STATUS | POLITICAL PERSPECTIVE | HDMA RECOMMENDATION/ POLICY CONSIDERATIONS |
|---|---|---|---|
| | jurisdiction in the country to pass such a law. HDMA anticipates more state legislation in 2013. | | |
| ***E-Prescribing*** | E-prescribing is a mechanism to better monitor controlled substance prescriptions. From state to state, regulations vary in allowing for e-prescribing of controlled substances. Some states allow for e-prescribing for schedules II-V, some limit e-prescribing to schedules III-V, some states prohibit e-prescribing and some states lack regulatory clarity. | Historically, HDMA has not been involved in this issue. However, e-prescribing could provide more real-time data to supplement data available through the PDMPs.<br><br>NACDS has been supportive of such proposals. NCPA has also been supportive; however, they have noted some of the challenges for independent pharmacy including installation and transactions costs, the costs associated with training staff and having to call back physicians regarding incomplete information on prescriptions, the compatibility of technology systems, and the need to have two-way communications with prescribers.<br><br>While there is a possibility for Congressional activity on this issue, there is currently no federal legislation on e-prescribing. States became more active on this issue after the DEA issued their Interim Final Rule in 2010, making changes to relevant state rules and regulations necessary. | HDMA should consider engaging with the pharmacy community on this issue to determine if there is a role for HDMA to advocate for increased or even mandatory e-prescribing for controlled substances.<br><br>**POLICY QUESTION:**<br>**Should HDMA advocate for mandatory e-prescribing for controlled substances, along with NACDS?** |
| ***Online Pharmacy*** | **FEDERAL ONLY** - Public Law 112-144 (S. 3187, PDUFA Reauthorization) | Pharmacy supports efforts to eliminate illegal Internet pharmacy operations. | HDMA currently supports efforts to eliminate illegal Internet pharmacy |

| ISSUE | STATUS | POLITICAL PERSPECTIVE | HDMA RECOMMENDATION/ POLICY CONSIDERATIONS |
|---|---|---|---|
| | requires the GAO to submit a study not later than 1 year after enactment to describe any problems posed by Internet pharmacy websites that violate Federal or State law.<br><br>Pending legislation remains which would require an in-person medical evaluation and a "valid prescription," establishes a registry of legitimate online pharmacy websites, and mandates an consumer advocacy campaign to improve patient understanding of how to safely purchase drugs over the internet. | Although there are concerns that legislation regulating online pharmacy further could negatively impact legitimate online pharmacies (such as those owned by pharmacy chains).<br><br>HDMA has been informally participating in the Alliance for Safe Online Pharmacies which includes a broad group of stakeholders including patient groups, pharmacy groups, pharmaceutical companies, boards of pharmacy and public health organizations. | operations.<br><br>We work closely with the pharmacy community to evaluate the impact of broader online pharmacy bills. |
| ***Pill Mills*** | **FEDERAL** - Legislation to identify "pill mills" and increase penalties for those operating practices "outside the scope of the prevailing standards of medical practice in the community in relation to the prescribing or dispensing of controlled prescription drugs" has been introduced. At this time, this proposal is also tied to rescheduling hydrocodone-combination products.<br><br>**STATE** - With the emergence of some pain management clinics operating as "pill mills" several states have introduced bills to license pain clinics and toughen penalties for those who knowingly operate a non-registered clinic. States such as Florida and Ohio | At the federal level, HDMA has only focused on the rescheduling sections of the pill mill bills.<br><br>One of the political considerations with this legislation and others related to pill mills is how "pill mill" is defined.<br><br>In the states, HDMA supports the appropriate state licensing requirements for entities operating as pain management clinics. Opposition to some of the issues involved has come from the Pain Care Forum and some state medical groups. | HDMA should support legislation to increase penalties for those operating pill mills and consider becoming more visible with our support.<br><br>State level - Other issues that are sometimes included in such legislation are wholesaler controlled substance sales reporting and customer due diligence. |

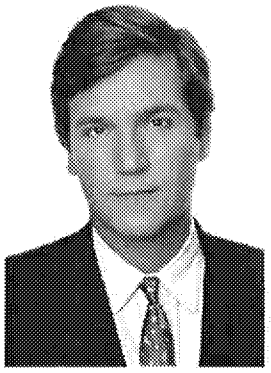
| ISSUE | STATUS | POLITICAL PERSPECTIVE | HDMA RECOMMENDATION/ POLICY CONSIDERATIONS |
|---|---|---|---|
| | have passed legislation in the last two years.<br><br>These types of clinics inappropriately dispense drugs that have the highest potential for abuse and diversion with little or no medical examinations. The rise in these clinics has directly contributed to the increase in prescription drug abuse across the country. | | |
| ***Prescription Drug Monitoring Programs*** | **FEDERAL** - Public Law 112-144 (S. 3187, PDUFA Reauthorization) establishes interoperability standards (ID MEDS Act) for prescription drug monitoring programs to facilitate information sharing across state lines.<br><br>Other legislative proposals under consideration include the reauthorization of NASPER and other funding mechanisms for establishment or expansion of PDMPs.<br><br>**STATE** - To date, 49 states have passed legislation establishing a PDMP. Missouri is the only state that has not approved it.<br><br>In addition, in 2011, NABP launched their PDMP InterConnect program. This program facilitates the transfer of PDMP | The states have more closely considered the specific implementation issues related to PDMPs such as: who should have access to PDMP data (pharmacies, providers, law enforcement), should participation be mandatory and who will pay for the PDMP. To date, these issues have not surfaced at the federal level.<br><br>NACDS supports PDMP requirements that have minimal administrative burden for pharmacies. Following are examples of issues that NACDS opposes: mandating that pharmacists check the database prior to dispensing; real-time data reporting and processing; and, reporting any over-the-counter "drugs of concern" that are not listed in Schedule II through V.<br><br>While the AMA also supports the use of PDMPs to combat prescription drug | HDMA currently supports efforts to increase interoperability of PDMPs and increased federal funding/grants for PDMPs.<br><br>**POLICY QUESTIONS:**<br>• Should HDMA support mandatory participation by providers and pharmacies?<br><br>• If HDMA advocates for mandatory participation, how will we respond to who will pay for the program? |

| ISSUE | STATUS | POLITICAL PERSPECTIVE | HDMA RECOMMENDATION/ POLICY CONSIDERATIONS |
|---|---|---|---|
| | data across state lines. As of May 2012, fourteen states have agreed to participate. | abuse, they have the following concerns: Access to data should be tightly controlled with access to and sharing of PDMP data complying with HIPAA and be focused on health care treatment decisions. The AMA states that for PDMPs to be useful for prescribers, data must be available in real-time. In addition, the AMA indicates that if a state wants increased physician participation, the PDMP should focus on educational instead of criminal activities. | |
| ***Prescription Drug Diversion Commission (NACDS proposal)*** | **FEDERAL ONLY** - NACDS has circulated a proposal on the Hill urging Congress to establish a commission to include participation from DEA, FDA, ONDCP, CMS, patient groups, pharmacy groups, prescriber and other provider groups, prescription drug wholesaler groups, pharmaceutical companies, public policy experts, state attorneys general, and law enforcement officials including groups representing local law enforcement. This commission would be responsible for developing recommendations and reviewing policy areas related to prescription drug abuse. | NACDS is trying to have this proposal included in a moving legislative vehicle this year. They have asked for our support on this initiative. | HDMA should conceptually support this; however, we have not seen this written in specific legislative language and would need to further evaluate. |
| ***Wholesalers Prohibited from Purchasing from Pharmacies*** | **FEDERAL** - Legislation was introduced to, in part, prohibit wholesalers from purchasing from pharmacies (with an | HDMA is on the record supporting this prohibition at the federal level. | This could be an opportunity for HDMA to proactively develop state language that includes requirements |

| ISSUE | STATUS | POLITICAL PERSPECTIVE | HDMA RECOMMENDATION/ POLICY CONSIDERATIONS |
|---|---|---|---|
| | exemption for returns). In August 2012 NABP announced their support for federal legislation on this issue.<br><br>**STATE** - This issue has not been introduced at the state level. | This issue was considered by SGAC in the past but it was ultimately decided to not move forward because of concerns with returns and pharmacy reaction. | that HDMA members have already incorporated into their business operating procedures.<br><br>**POLICY QUESTION:**<br>Should HDMA develop state language that would prohibit wholesalers from purchasing product from pharmacies (with exceptions for returns)? |
| ***Model federal bill*** | Over the past several years, HDMA members have taken proactive steps, above what is required in the DEA regulations, to evaluate their customers in the course of doing business to identify potential diversion, such as asking them questions about their business and the types of products they intend to purchase, whether their facility has been inspected by DEA or the state regulatory authority, and other information that may help distributors evaluate their customers and their orders.<br><br>HDMA members have also taken extensive steps to identify and report suspicious orders, in many cases beyond what is required in the DEA regulations. | From a political perspective, it could be an opportunity for HDMA to proactively develop a model bill outlining some of the practices that HDMA members have already incorporated into their business operating procedures, as well as other issues that HDMA supports in an effort to curb prescription drug abuse.<br><br>This would allow for us to go to the hill and ask for more regulation and certainty by having language in statute and eventually in regulation. | HDMA should consider the value of proactively developing legislation to codify business practices that relate to preventing diversion.<br>**POLICY QUESTION:**<br>• Should HDMA develop language that could standardize due diligence requirements and clarify suspicious order monitoring?<br><br>• Should HDMA develop language to also include the other issues that we already support to curb prescription drug abuse as part of a model bill? |

**Keith Flanagan**
**Senior Health Counsel**
**U.S. Senate Committee on Health, Education, Labor & Pensions (HELP)**

Keith concentrates in FDA and health matters. He led negotiations for Senate Republicans over the last two years on the successful enactment of the FDA user fee package, including the reauthorization of the drug and device programs and the creation of new user fees to fund applications for generic and biosimilar products. From 2010-2007, he advised HELP Committee Ranking Member Enzi – who also sits on the Finance Committee – regarding reauthorization of the Best Pharmaceuticals for Children Act, reauthorization of the Pediatric Research Equity Act, the Pediatric Medical Device Safety and Improvement Act of 2007, the Medical Device User Fee Amendments of 2007, the Genetic Information Nondiscrimination Act, the Wellstone-Domenici Mental Health Parity and Addiction Equity Act, the biosimilar; PCORI; IPAB and CMMI provisions of the Patient Protection and Affordable Care Act, the FDA Food Safety Modernization Act and the James Zadroga 9/11 Health and Compensation Act. In 2005-2006, he conducted Congressional investigations regarding FDA and medical product manufacturers. Keith formerly concentrated in outsourcing, information technology and corporate matters at SNR Denton. He earned his BA from Colgate and his JD from the University of Southern California.



## Tucker Carlson

***Contributor, FOX News; Editor-in-Chief, The Daily Caller and Senior Fellow, The Cato Institute***

***A Look at the Obama Administration, Congress and the 2012 Elections***

With a divided Congress, an alienated electorate and an Obama Administration that has been thrown off from its ambitious agenda, it is safe to say that we live in interesting political times. In this penetrating look at today's political climate, FOX News Contributor Tucker Carlson takes audiences behind closed doors, offering a candid, up-to-the-moment look at events as they unfold. From a look at Congress and the Obama Administration to his take on Governor Mitt Romney, the 2012 Republican Presidential candidate, you can always count on Tucker for a witty, informative and frank take on today's news.

***About the Speaker***

Tucker Carlson is a veteran journalist and political commentator, currently working for the Fox News Channel. Carlson is also the editor-in-chief of *TheDailyCaller.com,* one of the largest and fastest growing news sites in the country. Carlson joined Fox from MSNBC, where he hosted several nightly programs. Previously he was the co-host of *Crossfire* on CNN, where he was the youngest anchor in the history of that network. During the same period, Carlson also hosted a weekly public affairs program on PBS.

A longtime writer, Carlson has reported from around the world, including dispatches from Iraq, Pakistan, Lebanon and Vietnam. He has been a columnist for *New York* magazine and *Reader's Digest*. He currently writes for *Esquire* and *The New York Times* magazine. Carlson began his journalism career at the *Arkansas Democrat-Gazette* newspaper in Little Rock. His most recent book is entitled, *Politicians, Partisans and Parasites: My Adventures in Cable News*. In 2006, he appeared on ABC's *Dancing with the Stars.*

Carlson is currently working on his third book.

# Center for Medicaid and CHIP Services

# Myers and Stauffer LC

## Draft Methodology for Calculating the National Average Drug Acquisition Cost (NADAC)

June 28, 2012

# Topics

- Welcome and Introductions
- Level of Reporting
- Data Sources
- Data Collection and Survey Process
- NADAC Calculation
- NADAC Updates
- NADAC Help Desk
- NADAC File

# What is the NADAC?

National Average Drug Acquisition Cost (NADAC) is the national average invoice price that retail community pharmacies pay to acquire drug products.

# Level of Reporting

- CMS covered outpatient prescription and over-the-counter drugs
- Specialty pharmacies will not be included in the survey at this time
- NADAC will be reported at the 11-digit National Drug Code (NDC) level
- One NADAC will be reported per NDC
  - Acquisition costs collected from independent and chain pharmacies will be averaged into a single NADAC

# Level of Reporting

- NADAC will be calculated at the drug grouping and CMS drug category level
  - NDCs for drugs that are pharmaceutically equivalent (active ingredient, strength, dosage form, route of admin) will be grouped together
  - NDCs classified as either single source (S), innovator multiple source (I) or non-innovator multiple source (N)
- Separate NADACs calculated for S/I drugs and N drugs
- NADACs will be applied to NDCs according to their S/I/N status on the CMS file

# Level of Reporting (cont.)

## Example 1 – Single Source Drug

| Drug Grouping | NDC | Drug Category | NADAC |
|---|---|---|---|
| Crestor 10mg tablet | xxxxx-xxxx-x1 | S/I | 2.00000 |
| Crestor 10mg tablet | xxxxx-xxxx-x2 | S/I | 2.00000 |

# Level of Reporting (cont.)

## Example 2 – Innovator Multiple Source Drug

| Drug Grouping | NDC | Drug Category | NADAC |
|---|---|---|---|
| Lipitor 10mg tablet | xxxxx-xxxx-x3 | S/I | 2.00000 |
| Lipitor10mg tablet | xxxxx-xxxx-x4 | S/I | 2.00000 |

# Level of Reporting (cont.)

## Example 3 – Non-Innovator Multiple Source Drug

| Drug Grouping | NDC | Drug Category | NADAC |
|---|---|---|---|
| atorvastatin 10mg tablet | xxxxx-xxxx-x5 | N | 1.00000 |
| atorvastatin 10mg tablet | xxxxx-xxxx-x6 | N | 1.00000 |

# Level of Reporting (cont.)

- In cases where the S/I/N designation for a NDC does not correspond with the brand/generic designation commonly used by States for reimbursement purposes, an override process is being developed
- The goal of the override process is to address cases where the S/I/N designation would not accurately reflect the reimbursement policy utilized by the States
- CMS will review and approve proposed overrides

# Data Sources

- CMS covered outpatient drug product file from Medicaid.gov
- National pharmacy compendia file used to identify individual pharmacy characteristics and sampling population
- Pharmacy drug acquisition costs collected through monthly surveys of invoice pricing
- Multiple national drug compendia for:
  - NDC validation
  - Drug name, strength, dosage form, package size, billing unit
  - Medicaid drug rebate DESI code
  - Published pricing data

# Survey and Data Collection Processes

- Monthly national survey – all 50 states and the District of Columbia
- Random sample of 2,000 – 2,500 pharmacy stores per month
- Independent and Chain pharmacies (excludes specialty pharmacies)
- Voluntary submissions
- Requesting drug invoice purchase records from previous month

# Survey and Data Collection Processes (cont.)

- Invoice records should contain NDC, unit purchase price paid, invoice purchase date, quantity purchased
- Survey request letters will be sent to arrive on or about the first day of each month
- Chains may request that all surveys be sent to a corporate contact and via email only
- Pharmacies are asked to respond within 2 weeks
- Reminder notices will be sent following initial mailing

# Survey and Data Collection Processes (cont.)

- Invoice records may be sent in electronic or hard copy format
- Email, fax or mail is acceptable
- Invoice records will not be returned so pharmacies should send copies
- If pharmacy submits records voluntarily and identifies information as confidential, the information will not be disclosed except as required by law
- Information that is published will not include identifiable data to an individual or chain pharmacy

# Survey and Data Collection Processes (cont.)

- Pharmacy submissions are tracked in a receipt log
  - Response rates
  - Independent and chain representation
- Data are preliminarily reviewed to determine completeness and reasonableness of data
- Data is entered or loaded into database
- Quality assurance procedures are applied (e.g., valid and active NDCs, costs do not equal AWP, etc.)
- Data submitted will remain under the control of CMS
- Electronic and hard copies are stored securely